

§ 7.22a

(5) Alcohol content in accordance with § 7.71, for malt beverages that contain any alcohol derived from added flavors or other added nonbeverage ingredients (other than hops extract) containing alcohol.

(b) On the brand label or on a separate label (back or front):

(1) In the case of imported malt beverages, name and address of importer in accordance with § 7.25.

(2) In the case of malt beverages bottled or packed for the holder of a permit or a retailer, the name and address of the bottler or packer, in accordance with § 7.25.

(3) Alcoholic content, when required by State law, in accordance with § 7.71.

(4) A statement that the product contains FD&C Yellow No. 5, where that coloring material is used in a product bottled on or after October 6, 1984.

(5) [Reserved]

(6) *Declaration of sulfites.* The statement “Contains sulfites” or “Contains (a) sulfiting agent(s)” or a statement identifying the specific sulfiting agent where sulfur dioxide or a sulfiting agent is detected at a level of 10 or more parts per million, measured as total sulfur dioxide. The sulfite declaration may appear on a strip label or neck label in lieu of appearing on the front or back label. The provisions of this paragraph shall apply to:

(i) Any certificate of label approval issued on or after January 9, 1987;

(ii) Any malt beverage bottled on or after July 9, 1987, regardless of the date of issuance of the certificate of label approval; and,

(iii) Any malt beverage removed on or after January 9, 1988.

(7) *Declaration of aspartame.* The following statement, in capital letters, separate and apart from all other information, when the product contains aspartame in accordance with Food and Drug Administration (FDA) regulations:

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“PHENYLKETONURICS: CONTAINS PHENYLALANINE.”

(Paragraph (b)(6) approved by the Office of Management and Budget under Control No. 1512–0469)

[T.D. 6521, 25 FR 13859, Dec. 29, 1960, as amended by T.D. ATF-94, 46 FR 55097, Nov. 6, 1981; T.D. ATF-150, 48 FR 45557, Oct. 6, 1983; T.D. ATF-220, 50 FR 51852, Dec. 20, 1985; T.D. ATF-236, 51 FR 34710, Sept. 30, 1986; T.D. ATF-282, 54 FR 7162, Feb. 16, 1989; T.D. ATF-312, 56 FR 31077, July 9, 1991; T.D. ATF-339, 58 FR 21231, Apr. 19, 1993; T.D. ATF-347, 58 FR 44132, Aug. 19, 1993; T.D. TTB-12, 69 FR 33574, June 16, 2004; TTB T.D.-21, 70 FR 234, Jan. 3, 2005]

§ 7.22a Voluntary disclosure of major food allergens.

(a) *Definitions.* For purposes of this section the following terms have the meanings indicated.

(1) *Major food allergen.* Major food allergen means any of the following:

(i) Milk, egg, fish (for example, bass, flounder, or cod), Crustacean shellfish (for example, crab, lobster, or shrimp), tree nuts (for example, almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or

(ii) A food ingredient that contains protein derived from a food specified in paragraph (a)(1)(i) of this section, except:

(A) Any highly refined oil derived from a food specified in paragraph (a)(1)(i) of this section and any ingredient derived from such highly refined oil; or

(B) A food ingredient that is exempt from major food allergen labeling requirements pursuant to a petition for exemption approved by the Food and Drug Administration (FDA) under 21 U.S.C. 343(w)(6) or pursuant to a notice submitted to FDA under 21 U.S.C. 343(w)(7), provided that the food ingredient meets the terms or conditions, if any, specified for that exemption.

(2) *Name of the food source from which each major food allergen is derived.* Name of the food source from which each major food allergen is derived means the name of the food as listed in paragraph (a)(1)(i) of this section, except that:

(i) In the case of a tree nut, it means the name of the specific type of nut (for example, almonds, pecans, or walnuts); and

(ii) In the case of Crustacean shellfish, it means the name of the species of Crustacean shellfish (for example, crab, lobster, or shrimp); and

(iii) The names “egg” and “peanuts”, as well as the names of the different types of tree nuts, may be expressed in either the singular or plural form, and the name “soy”, “soybean”, or “soya” may be used instead of “soybeans”.

(b) *Voluntary labeling standards.* Major food allergens (defined in paragraph (a)(1) of this section) used in the production of a malt beverage product may, on a voluntary basis, be declared on any label affixed to the container. However, if any one major food allergen is voluntarily declared, all major food allergens used in production of the malt beverage product, including major food allergens used as fining or processing agents, must be declared, except when covered by a petition for exemption approved by the appropriate TTB officer under § 7.22b. The major food allergens declaration must consist of the word “Contains” followed by a colon and the name of the food source from which each major food allergen is derived (for example, “Contains: egg”).

(c) *Cross reference.* For mandatory labeling requirements applicable to malt beverage products containing FD&C Yellow No. 5, sulfites, and aspartame, see §§ 7.22(b)(4), (b)(6), and (b)(7).

[T.D. TTB-53, 71 FR 42269, July 26, 2006]

§ 7.22b Petitions for exemption from major food allergen labeling.

(a) *Submission of petition.* Any person may petition the appropriate TTB officer to exempt a particular product or class of products from the labeling requirements of § 7.22a. The burden is on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the finished product or class of products, as derived by the method specified in the petition, either:

(1) Does not cause an allergic response that poses a risk to human health; or

(2) Does not contain allergenic protein derived from one of the foods identified in § 7.22(a)(1)(i), even though a major food allergen was used in production.

(b) *Decision on petition.* TTB will approve or deny a petition for exemption submitted under paragraph (a) of this section in writing within 180 days of receipt of the petition. If TTB does not provide a written response to the petitioner within that 180-day period, the petition will be deemed denied, unless an extension of time for decision is mutually agreed upon by the appropriate TTB officer and the petitioner. TTB may confer with the Food and Drug Administration (FDA) on petitions for exemption, as appropriate and as FDA resources permit. TTB may require the submission of product samples and other additional information in support of a petition; however, unless required by TTB, the submission of samples or additional information by the petitioner after submission of the petition will be treated as the withdrawal of the initial petition and the submission of a new petition. An approval or denial under this section will constitute a final agency action.

(c) *Resubmission of a petition.* After a petition for exemption is denied under this section, the petitioner may resubmit the petition along with supporting materials for reconsideration at any time. TTB will treat this submission as a new petition.

(d) *Availability of information—(1) General.* TTB will promptly post to its public Web site, <http://www.ttb.gov>, all petitions received under this section as well as TTB’s responses to those petitions. Any information submitted in support of the petition that is not posted to the TTB Web site will be available to the public pursuant to 5 U.S.C. 552, except where a request for confidential treatment is granted under paragraph (d)(2) of this section.

(2) *Requests for confidential treatment of business information.* A person who provides trade secrets or other commercial or financial information in connection with a petition for exemption under this section may request that TTB give confidential treatment to that information. A failure to request confidential treatment at the time the information in question is submitted to TTB will constitute a